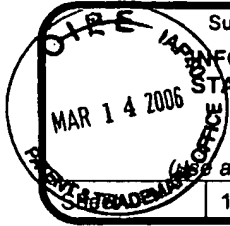


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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

Date Submitted:

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1 of 3

## Complete if Known

Application Number	10/677,227
Filing Date	10/03/2003
First Named Inventor	Hiroaki ITO
Group Art Unit	1646
Examiner Name	Prema MERTZ
Attorney Docket Number	053466-0365

## U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
PM	B1	5,888,510		Kishimoto et al.	03/30/1999	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
PM	B2	JP	8-208514		Chugai Pharmaceutical Co. Ltd.; Kishimoto CHUZO	08/13/1996		Abs
	B3	WO	96/00081	A1	Immunex Corporation	01/04/1996		
	B4	WO	97/38104	A	Applied Research Systems Ars Holding N. V.	10/16/1997		

## NON PATENT LITERATURE DOCUMENTS

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PM	B5	IGAKU, Vol. 51, No. 10, 1996, pgs. 111-121, with Partial Translation.	
PM	B6	Jpn. J. Clin. Immun., Vol. 20, No. 2, 1997, pgs. 87-94.	

Examiner  
Signature

Prema Mertz

Date  
Considered

10/21/06

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Sheet	4	of	2
		Application Number	Unassigned 15/677,227
		Filing Date	10/03/2003
		First Named Inventor	Hiroaki ITO et al.
		Group Art Unit	1646
		Examiner Name	Unassigned <i>Penna Muntz</i>
		Attorney Docket Number	053466-0365

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
PM	A1	WO	96/40966	A1	Private Biologicals Corporation	12/19/1996		
	A2	JP	7-324097			12/12/1995		
	A3	JP	8-311098			11/26/1996		
	A4	JP	8-245414			09/24/1996		
	A5	JP	9-235276			09/09/1997		
	A6	JP	8-99996			04/16/1996		
	A7	JP	8-50829			09/03/1996		
	A8	WO	96/409966			12/19/1996		
	A9	WO	96/38481		The Board of Regents of the University of Oklahoma	12/05/1996		
	A10	EP	0 811 384		SEIYAKU et al.	12/10/1997		
	A11	WO	99/64069		Ophidian Pharmaceuticals, Inc.	12/16/1999		

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PM	A12	POWRIE et al., "Inhibition of Th1 Responses Prevents Inflammatory Bowel Disease In scid Mice Reconstituted With CD45Rbhi CD4+ T Cells", Immunity, Vol. 1:553-562, (1994).		
	A13	TAKAGI et al., "Blockage Of Interleukin-6 Receptor Ameliorates Joint Disease In Murine Collagen-Induced Arthritis", Arthritis Reheumatism, Vol. 41(12):2117-2121, (1998).		
	A14	MITSUYAMA et al., "Soluble Interleukin-6 Receptors In Inflammatory Bowel Disease; Relation To Circulating Interleukin-6", Gut, Vol. 36:45-49, (1995).		
	A15	VAN DULLEMEN et al., "Treatment Of Crohn's Disease With Anti-Tumor Necrosis Factor Chimeric Monoclonal Antibody (ca2)", Gastroenterology, Vol. 109:129-135, (1995).		
	A16	SASAJIMA et al., "Changes in Serum Cytokine Profile During Treatment of Ulcerative Colitis", Journal of Gastroenterology and Hepatology, December 1997, page A274, vol. 12, no. SUPPL., XP-001105732.		

Examiner Signature	<i>Penna Muntz</i>	Date Considered	10/24/06
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Substitute for form 1449B/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> Date Submitted: October 3, 2003 (use as many sheets as necessary)		<b>Complete if Known</b>	
Application Number	Unassigned — 10/677, 227		
Filing Date	10/03/2003		
First Named Inventor	Hiroaki ITO et al.		
Group Art Unit	1646		
Examiner Name	Unassigned — <i>Premia Menz</i>		
Attorney Docket Number	053466-0365		
Sheet	2	of	2

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Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				

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PM	A17	FUNAKOSHI et al., "Spectrum of Cytokine Gene Expression in Intestinal Mucosal Lesions of Crohn's Disease and Ulcerative Colitis", Digestion, January 1998, pages 73-78, vol. 59, no. 1, Basel, China, XP-001064174.	
	A18	TATEISHI et al., "Role of Cytokines in Experimental Colitis: Relation to Intestinal Permeability", Digestion, 1997, pages 271-281, vol. 58, no. 3, Basel, China, XP-001095980.	
	A19	SEIDMAN et al., "Nutritional Issues in Pediatric inflammatory Bowel Disease", Journal of Pediatric Gastroenterology and Nutrition, 1991, pages 424-438, vol. 12, no. 4, Raven Press, Ltd., New York, XP-001105792.	
	A20	ROGLER et al., "Cytokines in Inflammatory Bowel Disease," World J. Surg. Vol. 22, No. 4, April 1998, pp. 382-389.	
	A21	KMIEC, "Cytokines in Inflammatory Bowel Disease," Arch. Immunol. Ther. Exp. (Warsz), Vol. 46, No. 3, 1998, pp. 143-155.	
	A22	HOGZAND et al., "Selective Immunomodulation in Patients With Inflammatory Bowel Disease-Future Therapy or Reality?" Neth. J. Med. February 1996, Vol. 48, No. 2, pp. 64-67.	

Examiner Signature	<i>Premia Menz</i>	Date Considered	10/24/06
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